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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,585	10/12/2000	Ger Van den Eng	Cyto-Nozzle-Div	2640

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EXAMINER

LUDLOW, JAN M

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 10/03/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

Applicant(s)

09/689,585

ENGH, GER VAN DEN

Examiner

Art Unit

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become "ABANDONED" (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83-110 is/are pending in the application.
- 4a) Of the above claim(s) 97-110 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 83-87, 89, 91, 92 and 94-96 is/are rejected.
- 7) ☒ Claim(s) 88, 90 and 93 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3/3 6) ☐ Other: _____

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 44-55, drawn to a method of forming a droplet by continuous convergence, classified in class 436, subclass 180.
- II. Claims 56-82, drawn to an apparatus for forming a droplet by continuous convergence, classified in class 422, subclass 100.
- III. Claims 83-96, drawn to an apparatus for forming a droplet including a nozzle tip seal, classified in class 422, subclass 100.
- IV. Claims 97-110, drawn to a method for forming a droplet in a nozzle tip, classified in class 436, subclass 180.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method does not require the free fall area of the apparatus and the droplets can be formed by acoustic or other disruption following exit from the nozzle.

3. Inventions IV and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method does not require the particulars of the apparatus,

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e.g., a seal to which both the nozzle body and tip are responsive, a sheath introduction port, a substance introduction port and a free fall area below the nozzle tip in which the droplet forms.

4. Inventions (I, II) and (III, IV) are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions (I, II) has separate utility such as droplet formation using a nozzle with an integral tip. See MPEP § 806.05(d).

5. The restriction requirement with respect to the cancelled claims is provided for completeness of the record.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. In the paper filed September 17, 2002 a provisional election was made without traverse to prosecute the invention of group III, claims 83-85, claims 86-96 being added to this group by amendment. Affirmation of this election must be made by applicant in replying to this Office action. Claims 97-110 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. If the method claims were amended to be commensurate in scope with the apparatus claims,

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i.e., to include all the limitations of the apparatus claim and at least one positively recited method step, such as "flowing sheath and substance fluid through the nozzle volume to form droplets in the free fall area," rejoinder would be appropriate.

9. The drawings are objected to because black dots from the photocopier are seen in the figures. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

10. Claims 87 and 93 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A flow cytometer nozzle of the claimed structure and having an oscillator powered by less than 100 mV, but not requiring direct coupling of the oscillator to the fluid (p. 11, lines 14-17), unidirectional coupling of the oscillator (p. 13, lines 2-4) and continuous convergence of the nozzle body (p. 14, lines 13-15), which are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant has not enabled one of ordinary skill in the art to make or use a nozzle of the claimed structure that uses less than 100 mV to the oscillator in that the disclosure does not teach that the manner of attaching the tip imparts any of the energy savings (p. 16, paragraph 3). Claim 87 lacks two of the essential features required to achieve the low power usage (direct coupling and nozzle convergence) and claim 93 lacks all three features. Applicant has not shown that including only one or none of the energy saving features will produce a low energy usage nozzle.

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11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 83-86, 89, 91-92, 94-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollinger et al (4515274).

Hollinger teaches a nozzle body 14 with sheath 23B and sample 23A inlets. Nozzle tip 16, 14 is joined to the body. A structure (medium hatching between outside of 16 and interior surface of 14) is between the body and tip. There is a joint between the body and tip at the inner edges of the top of part 16, constituting the instant "edge insert". Portion 18 is convergent near the sample outlet (instant "flow convergence zone"). A piezoelectric oscillator 36 coupled unidirectionally (i.e., laterally) to part 14 is provided.

Hollinger fails to teach that the parts are sealed or the claimed power source.

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It would have been obvious to seal the parts of Hollinger together in order provide a leak-free flow path to minimize loss of sample, sheath fluid and/or pressure in the closed system. It would have been obvious to provide a power source to power the piezoelectric crystal with minimum power in order to make it oscillate as described.

14. Claims 88, 90 and 93 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter: Hollinger fails to teach or suggest a directional isolator located between the oscillator and the nozzle body, a sample fluid inlet position adjuster or continuously convergent tip and body.

16. Note that Sage ('971) teaches sample tube lateral adjustment, but that there is no motivation to combine with Hollinger in that the nozzle body structures are significantly different.

17. Note that Buchanan et al ('745) teach a tip attached similarly to that of the instant invention, but does not constitute prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml
September 30, 2002